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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,521	02/15/2000	PETER E. NIELSEN	ISIS-3070	8096
32650	7590	12/01/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,521	Applicant(s) NIELSEN, PETER E.	
	Examiner J. D. Schultz, Ph.D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of Application/Amendment/Claims

Applicant's response filed September 16, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 17, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed January 10, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure, for the same reasons as cited in the Official action mailed June 17, 2004. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the reference that variables R_i and R_j may be taken separately or together, and are selected separately or together from the group consisting of alkyl, steroid, or lipid.

Applicants argue that "More recent advances in the structure and synthesis of PNAs are illustrated in WO 93/12129 and U.S. Patent 5,539,082, issued July 23, 1996, the contents of both being herein incorporated by reference", serves to direct particular attention to specific portions of the referenced document where the subject matter being incorporated may be found. This is not agreed, with because this reference is considered generic, and is not considered to direct one of skill with any precision to the entities that were contemplated from the referenced

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document teaching the instantly added alkyl, lipid or steroid moieties. Thus, under the guidelines of M.P.E.P. § 608.01(p), the addition to the specification of alkyl, lipid and steroid from the application corresponding to U.S. Patent No. 5,539,082 is considered to constitute new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments, Double Patenting

Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,773,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 encompasses the instantly claimed chemical structure of claims 23 and 24, for the same reasons as that cited in the Official action mailed June 17, 2004.

Applicants have argued that the linking moiety between "A" and "J" of the issued '571 patent (i.e., $-\text{C}(\text{O})\text{CH}_2$) is different from the instant composition, because only structure IIb could provide such a linking moiety, which applicants argue is impossible because the 571 patent, further requires that compositions having formula IIb linkers have either at least one "A" group of formula (IIc) or that at least one of y or z is not 1 or 2. Applicants argue that each of these limitations places the claims in the '571 patent outside the instant claims, because claims 23 and 24 are not directed to compounds that include a linker of formula IIc, or have a structure where "y" or "z" from claim 1 of the 571 patent are not 1 and 2.

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This position is not adopted, because the instantly claimed structure can be envisioned when at least one of y or z is not 1 or 2, contrary to applicants arguments. For example, condition “(c)” of claim 1 states that in order for said condition to be in effect, that

“(c) A is a group of formula (IIa), or (IIb), J is N or R^3N^+ , provided at least one of y or z is not 1 or 2”...

However, when A=IIb, and $J=R^3N^+$, where R^3 is taken to be C1-alkyl, and where $z=0$, and $y=3$, all the limitations of this condition and the claim in general are met, and the patented structure thus embraces the instant claim 23. Furthermore, since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met. The rejection is therefore maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,700,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 encompasses the instantly claimed structure of claim 23.

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Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an "R⁷" moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an "R^h" moiety which consists of one of OH, NH₂, or NHLysNH₂, and "Rⁱ" and "R^j" moieties, which are independently a fluorescent group or a lipophilic group, or when Rⁱ and R^j are taken together, are a lipophilic group.

Patented claim 1 claims structure I, which has an "L" moiety that is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 1 also contain "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, *r* is zero, *s* is 1, R¹ and R² are both H, and wherein "B" is R³N which is an N-C₂-alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 1 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R⁷ moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as -NR³CO- where R³ is H, "Q" is selected as -CO₂H-, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

2. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,451,968. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 19 encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to the invention as described above.

Patented claim 19 claims structure I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 19 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, *r* is zero, *s* is 1, R^1 and R^2 are both H, and wherein "B" is R^3N which is an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 19 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as $-NR^3CO-$ where R^3 is H, "Q" is selected as $-CO_2H-$, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

3. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,165,720. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 3 encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to the invention as described above.

Claim 3 of the '720 patent claims PNA compounds conjugated to a fluorescent label, which is considered to embrace the instant invention, because the instant invention is essentially

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drawn to a PNA oligo conjugated to an amino acid labeled with a fluorescent group, and/or a lipophilic group. The specification also contemplates such compounds in liposomes.

4. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 6,350,853.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claims 1 and 5 encompass the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an "R⁷" moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an "R^h" moiety which consists of one of OH, NH₂, or NHLysNH₂, and "Rⁱ" and "R^j" moieties, which are independently a fluorescent group or a lipophilic group, or when Rⁱ and R^j are taken together, are a lipophilic group. Claim 24 is drawn to the same structure in a liposome.

Patented claim 1 claims PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an "R⁷" moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an "R^h" moiety which consists of one of OH, NH₂, or NHLysNH₂, and "Rⁱ" and "R^j" moieties, which are independently or taken together an alkyl lipid or steroid, which are considered lipophilic groups. Patented claim 5 teaches the instant structure in a liposome. The patented claims thus anticipate the instant claims.

5. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 5,837,459. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 9 encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an "R⁷" moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an "R^h" moiety which consists of one of OH, NH₂, or NHLysNH₂, and "Rⁱ" and "R^j" moieties, which are independently a fluorescent group or a lipophilic group, or when Rⁱ and R^j are taken together, are a lipophilic group, and to compositions comprising diluents or liposomes.

Patented claim 9 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 9 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, *r* is zero, *s* is 1, R¹ and R² are both H, and wherein "B" is R³N which is an N-C₂-alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 9 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R⁷ moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as -NR³CO- where R³ is H, "Q" is selected as -CO₂H-, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

6. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 5,874,213. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 26 uses a structure which encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to the invention as described above.

Patented claim 26 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 26 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, r is zero, s is 1, R^1 and R^2 are both H, and wherein "B" is R^3N which is an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 26 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as $-NR^3CO-$ where R^3 is H, "Q" is selected as $-CO_2H-$, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

7. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,610,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 1 uses a structure which encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to the invention as described above.

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Patented claim 1 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 1 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, r is zero, s is 1, R^1 and R^2 are both H, and wherein "B" is R^3N which is an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 1 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as $-NR^3CO-$ where R^3 is H, "Q" is selected as $-CO_2H-$, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

8. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,395,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 claims encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an " R^7 " moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an " R^h " moiety which consists of one of OH, NH_2 , or $NH-Lys-NH_2$, and " R^i " and " R^j " moieties, which are independently a fluorescent group or a lipophilic group, or when R^i and R^j are taken together, are a lipophilic group, and to compositions comprising diluents or liposomes.

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Patented claim 1 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 9 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from a structure where Y may be a single bond, r may be zero, s may be 1, R^1 and R^2 may be both H, and wherein "B" is R^3N which may be an N-C₂-alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 9 further contains a "T" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as -NR³CO- where R^3 is H, "Q" is selected as -CO₂H-, and "T" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

9. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,451,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 claims encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an " R^7 " moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an " R^h " moiety which consists of one of OH, NH₂, or NHLysNH₂, and " R^i " and " R^j " moieties, which are independently a fluorescent group or a lipophilic group, or when R^i and R^j are taken together, are a lipophilic group, and to compositions comprising diluents or liposomes.

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Patented claim 1 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 1 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, r is zero, s is 1, R^1 and R^2 are both H, and wherein "B" is R^3N which is an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 1 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as - NR^3CO - where R^3 is H, "Q" is selected as $-CO_2H$ -, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

10. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,713,602. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of producing the structure of patented claim 1 claims encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an " R^7 " moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an " R^h " moiety which consists of one of OH, NH_2 , or $NHLysNH_2$, and " R^i " and " R^j "

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moieties, which are independently a fluorescent group or a lipophilic group, or when R_i and R_j are taken together, are a lipophilic group, and to compositions comprising diluents or liposomes.

Patented claim 1 claims a process for making formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 9 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from a structure where Y may be a single bond, r may be zero, s may be 1, R^1 and R^2 may be both H, and wherein "B" is R^3N which may be an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 9 further contains a "T" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as $-NR^3CO-$ where R^3 is H, "Q" is selected as $-CO_2H-$, and "T" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

11. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,228,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an " R^7 " moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an " R^h " moiety which consists of one of OH, NH_2 , or $NHLysNH_2$, and " R^i " and " R^j "

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moieties, which are independently a fluorescent group or a lipophilic group, or when R_i and R_j are taken together, are a lipophilic group, and to compositions comprising diluents or liposomes.

Patented claim 1 claims formula I, which has an "L" moiety which is a nucleobase and corresponds to the nucleobase "L" moiety of instant claim 23. Patented claim 1 also contains "A" and "B" moieties, wherein the "A" moiety may be a carboxyl derived from structure IIb where Y is a single bond, r is zero, s is 1, R^1 and R^2 are both H, and wherein "B" is R^3N which is an N- C_2 -alkyl, whereby "A" and "B" thus correspond to the NCO structure of the instant claim 23 which links "L" to the peptide backbone. Patented claim 1 further contains a "C" moiety which may be a C-linked to the side chain of a naturally occurring amino acid and thus corresponds to the R^7 moiety of the instant claim 23. Finally, where "D" is selected as zero, "G" is selected as $-NR^3CO-$ where R^3 is H, "Q" is selected as $-CO_2H-$, and "I" is a steroid, the structure of instant claims 23 is considered to be taught. Since the disclosure describes preferred embodiments in liposomes and pharmaceutically acceptable diluents thereof, all claim limitations of claims 23 and 24 are considered to be met.

12. Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,770,738. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of patented claim 1 encompasses the instantly claimed structure of claim 23.

Claims 23 and 24 are drawn to PNA oligos up to 30 units long that comprise an "L" moiety which consists of a naturally occurring or non-naturally occurring nucleobase, an " R^7 " moiety which consists of the side chain of a naturally occurring or non-naturally occurring amino acid, an " R^h " moiety which consists of one of OH, NH_2 , or $NHLysNH_2$, and " R^i " and " R^j "

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JD Schultz, PhD

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